



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

GENAPP.002RA

(020728.0101)

PATENT

Applicant : Gopal ) Group Art Unit: 1636  
Reissue Appl. : 09/404,979 ) Examiner: McKelvey, T.  
Filed : September 22, 1999 )  
For : PEPTIDE-MEDIATED )  
GENE TRANSFER )

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JUN 20 2003

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DECLARATION UNDER 37 C.F.R. § 1.131

Honorable Commissioner for Patents  
Washington, D.C. 20231

Dear Sir:

I, T. Venkat Gopal, Ph.D., hereby declare that:

1. I am the named inventor of the above-identified reissue application number 09/404,979.

2. I am the original, first, and sole inventor of the subject matter disclosed and claimed in the pending reissue application.

3. I understand that a rejection was made in the pending reissue application based on U.S. Patent No. 5,994,109 (filed June 3, 1995) and, alternatively, Smith et al. WIPO Application No. WO 93/18759 (published September 30, 1993).

4. As shown by the facts discussed in this declaration and the accompanying exhibits the invention of the claims rejected in the pending reissue application was made prior to the date September 30, 1993, the international application date of the Smith et al. reference.

5. All of the work discussed below was performed in the United States by, or on behalf of, myself prior to September 30, 1993.

6. Prior to September 30, 1993, a peptide was manufactured on my behalf by STAR Biochemicals, Inc., 20916 Higgins Court, Torrance, California. The sequence of this synthetic peptide is nearly identical to the example sequence (Seq. ID No. 56) used in the original patent of the pending reissue application (column 10 of U.S. Patent No. 5,670,347). Attached as Exhibit 1 is a true and correct photocopy of an invoice from STAR Biochemicals for the production of the synthetic peptide, which has had the dates contained on the invoice redacted.

7. Prior to September 30, 1993, STAR Biochemicals provided a Certificate of Analysis demonstrating an amino acid analysis of the manufactured synthetic peptide, attached hereto as Exhibit 2. This analysis was consistent with that expected for the requested sequence.

8. Prior to September 30, 1993, I used the synthetic peptide manufactured by STAR Biochemicals to test its efficacy on the transfection of DNA into mammalian cells. Attached as Exhibit 3 is a true and correct photocopy of pages from my laboratory notebook which has had dates contained on the invoice redacted and the letters A through P replacing the dates. The entries were made prior to September 30, 1993, documenting experiments performed with the synthetic peptide in the United States. The synthetic peptide manufactured by STAR Biochemicals, Inc. is referred to as "Expression-1" in the exhibit.

9. Of particular interest to the issues of this case, at date A which is prior to September 30, 1993, cells were suspended along with Expression -1 for transfection. At date J also before September 30, 1993, the notebook indicates there are 50-60 good clones from the date A experiment whereas no clones are present for the LTA control and L1. In the comment for that date, I indicate the DNA will work "for any attached cell for tx [my abbreviation for "transfection"] using expression -1."

10. At date D, which is prior to September 30, 1993, I describe another experiment with Expression 1. This experiment is for "LTA tx [transfection] in suspension."

11. At date M, prior to September 30, 1993, I concluded in my laboratory notebook, as documented in Exhibit 3, that on the basis of my experiments "Expression -1" provided a stable transfection efficiency of 16%. The notebook states "∴ [my abbreviation for "therefore"] with LTA linear DNA with Expression -1 works very well. Tx [transfection] efficiency no. colonies/cells plated  $\times 10^2 = 16\%$ ." This value meets or exceeds the results shown in Table II of the original patent of the pending reissue application (column 10 of U.S. Patent No. 5,670,347).

12. To summarize, prior to September 30, 1993, I had (1) caused the production of a synthetic peptide that corresponds to the broadest claim in U.S. Patent No. 5,670,347; (2) used the resulting synthetic peptide to test its effect on the transfection of DNA into mammalian cells; (3) empirically demonstrated to my satisfaction that the synthetic peptide worked as I intended by providing highly efficient transfer and stable integration of DNA into a mammalian cell line.

13. Therefore, I believe that the invention of the rejected claims had been reduced to practice in the United States prior to the reference dates cited by the Examiner, i.e., before June 3, 1995 in case of U.S. Patent No. 5,994,109 and before September 30, 1993 in the case of WIPO Application No. WO 93/18759.

14. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful, false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the

United States Code and that such willful, false statements may jeopardize the validity of the application or patent issuing therefrom.

Respectfully submitted,

Dated: 5/9/03

By: T. Venkat Gopal  
T. Venkat Gopal